



THE EDINBURGH BRAIN BANK

INFORMATION BOOKLET FOR DONORS AND FAMILIES

Background

We are the only Brain Bank in Scotland.

We retrieve tissue samples from people with different illnesses and diseases, many of which are long-standing and degenerative, and from cases of sudden death.

The tissue donated to the bank is currently supporting research projects in the UK and around the world. In time this research could contribute to greater understanding of these diseases, helping to ultimately find cures and improve the lives of people who suffer from these conditions.

The Edinburgh Brain Bank supplies tissue to researchers all over the world, and operates on a non-profit basis. All processes and procedures have full research ethics approval. A panel of experts has examined the proposal and raised no objections from a medical ethics perspective. It is also a requirement that the medical records of donor's are made available for scrutiny by monitors from NHS Lothian and Health Improvement Scotland (HIS). Their role is to check that research is properly conducted and the interests of those involved are adequately protected.

Where does the tissue come from?

Research post-mortem examinations – these are limited post-mortem examinations that are carried out for specific research studies after discussion with, and consent/authorisation from, individuals and their families.

Procurator Fiscal post-mortem examinations – these are full post-mortem examinations instructed by the Procurator Fiscal that are primarily to establish cause of death. In full post-mortem examinations, samples are collected from all organs, including the heart, spleen, liver, lymph nodes and muscle. Authorisation for these samples to be used for research can be obtained from families.

What tissue is collected for research?

We collect a wide range of small tissue samples, depending on specific research studies.

The Brain Bank works closely with specialist medical groups elsewhere in the UK and abroad and small tissue samples may be sent to these other groups to support their ethically approved research.

What do we mean by tissue?

Tissue is the word used for a collection of specialised cells within the human body that perform a specific job. All organs, including the brain and spinal cord, are made up of tissue.

Why is tissue needed for research?

In Edinburgh, all tissue collected is made available for a wide range of research into various illnesses, including conditions such as Multiple Sclerosis, Motor Neurone Disease, Huntington's Disease, Parkinson's Disease, Multiple System Atrophy, Corticobasal Syndrome, Progressive Supranuclear Palsy, dementia, stroke and psychiatric conditions.

Studying tissue samples from people with and without different diseases, results in a collection of a wide variety of samples. Some samples may show early or advanced disease while others may be completely normal. Each of these makes an important contribution to research studies. Often, it is only through the study of large numbers of cases that significant observations can be made, which will increase our understanding of human disease.

Can people with specific illnesses or diseases take part?

Yes. By studying and contrasting tissues from people with and without specific illnesses, we hope to understand what goes wrong in specific diseases. This is vital if any treatments are to be discovered and developed in the future.

Can people who have died suddenly take part?

Yes. Sudden deaths are referred to the Procurator Fiscal who may request a full post-mortem examination. The post-mortem examination and any tests later carried out in the laboratory are undertaken to find the cause of death but this is also an opportunity to collect tissue samples for research.

Will family be able to view the body after full or limited post-mortem examination?

Yes. Your family will be able to view the body either before or after the post-mortem examination if they wish. All post mortem examinations, be they full or limited, are undertaken by highly skilled technicians.

What other information is required?

We request permission to access hospital records where applicable. Having access to detailed information about each donor's medical history means that researchers can match specific symptoms with any changes they see in the tissue samples.

What about confidentiality?

All paperwork and information obtained is stored securely in the Centre for Clinical Brain Sciences, University of Edinburgh where it will be retained indefinitely and remain strictly confidential. Every donor is given a unique identification code and all personal information is removed. Information may be shared in an anonymised form with other researchers, including commercial organisations that perform ethically approved research, but personal details are never shared with anyone. Regular update training is required for all brain bank staff and local courses are available through NHS Lothian and University of Edinburgh. The University has an ongoing policy for good practice in data protection and the senior member of the brain bank team monitors compliance with data protection.

How will the tissue be made available to researchers?

To help as many research projects as possible, some of the tissue samples will be divided into many sections. These samples and sections are stored safely and securely in the Edinburgh Brain Bank at the Centre for Clinical Brain Sciences, University of Edinburgh.

Researchers from the UK and around the world can request tissue from the Brain Bank to use in their research projects. Our panel of experts reviews each request for tissue before approving the projects we supply tissue to. Tissue is only released to research groups with peer reviewed funding. All tissue released will be completely anonymised to the research group and all identifying data is only known to senior core staff within the Brain Bank.

We cannot predict what type of project the tissue will be used for or where the research will be carried out. However, all research we support is ethically and scientifically approved and will help us to better understand different illnesses and diseases. Tissue may also be used for teaching purposes or in the training of healthcare professionals.

What about genetic research?

Samples of tissue are sometimes used for medical genetic research, which aims to discover the links between genes and disease. Genes can affect health in various ways; a gene abnormality may directly cause illness or more commonly, variations in genes may predispose to illnesses such as high blood pressure and psychiatric disorders. It is important to emphasise that these gene variations do not directly cause illness but in combination with other factors such as diet, smoking etc, they may make a disease more likely.

What about commercial research?

Research groups are sometimes asked by commercial groups if they may obtain samples for ethically approved medical research. This research is usually for the purpose of developing new drug treatments, which could eventually be marketed. Neither relatives nor the research groups profit financially from any developments of this kind. We never release tissues to a "middle man" who can then sell that tissue for profit, and we carefully review the proposed use of all requested tissues.

Are there any costs involved?

No. All costs will be met by the Brain Bank

Can organ and tissue donation for transplant still be done?

Yes. Donation of organs and tissue for transplant will take priority over tissue donation for research but we may be able to arrange research tissue donation after the organ/tissue donation process.

Can a whole body be donated to an Anatomy School after post-mortem examination?

No. Unfortunately, this is not possible as Anatomy Schools require the whole body intact.

What happens when the research is finished?

We carefully preserve the donated tissue samples by embedding them in paraffin wax or freezing them at -80° C. This means the tissue can be used for research for up to ten years or even longer. When the tissue is no longer suitable for research, we dispose of it lawfully.

Will the decision affect the funeral arrangements?

No, the funeral arrangements will not be affected by agreeing to donate tissue for research.

If there is agreement now can this be withdrawn at a later date?

Yes. Giving consent/authorisation for tissue to be used for research is entirely voluntary and withdrawal can be made at any time without giving a reason why. The donated samples will no longer be used for research and education and will be disposed of lawfully.

As regards tissue from post-mortem examinations requested by the Procurator Fiscal, all frozen samples will be lawfully disposed of and all samples embedded in paraffin wax will be retained as part of the deceased's medical record, which is normal practice. They will not be used for research.

Who has reviewed this study?

The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Lothian, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Where are the results of the research?

Researchers often publish their results in scientific journals. Please feel free to ask any questions now or in the future if you wish to find out more.

If there is a belief that any harm has been suffered by taking part in this study, there is a right to pursue a complaint and to seek any resulting compensation through NHS Lothian who is acting as the research sponsor. Details about this are available from the research team. Also as a patient of the NHS, you have the right to pursue a complaint to the Patient Liaison Manager, NHS Lothian Complaints Team, Waverley Gate 2nd Floor, 2 - 4 Waterloo Place, Edinburgh, EH1 3EG (0131 536 3370). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Lothian but you may have to pay your legal costs.

Thank you for taking the time to read this Information Sheet and for considering giving consent/authorisation for research

If you require further information or have any queries, please contact:

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